



**An die interessierte Partei / To whom it may concern**

**Dr. Stefan Dreiheller**  
Quality Unit / Regulatory Affairs

Date of issue: 03.09.2019  
Page 1/2  
Doc.-No. EIP-0025  
Revision 27

## **Undesired Substances**

MEGGLE products:

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100
- Lactose Monohydrate USP-NF / Ph. Eur. / JP: InhaLac® 70, InhaLac® 120, InhaLac® 230, InhaLac® 250, InhaLac® 251, InhaLac® 400, InhaLac® 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, RetaLac®, StarLac®

The mentioned substances mentioned in the list on page 2 are neither used as ingredients and technical aids nor are contained in ingredients or technical aids as intentionally added substances.

Manufacturing includes refining whereby processing aids (activated carbon and inorganic filter auxiliaries) are added to a hot solution of the unrefined lactose. With cooling, the desired crystals grow and the regular structure of the crystal tends to favour the desired material and exclude other kinds of particles and impurities. Thus, refining is a purification process leading to a higher purity.

The other compounds in co-processed excipients are purified substances, also.

Freundliche Grüße / Best regards

**Molkerei MEGGLE Wasserburg GmbH & Co. KG**

  
Dr. Stefan Dreiheller



## An die interessierte Partei / To whom it may concern

**Dr. Stefan Dreiheller**  
Quality Unit / Regulatory Affairs

Date of issue: 03.09.2019

Page 2/2

Doc.-No. EIP-0025

Revision 27

## Undesired Substance List

Alkyl phenols and their ethoxylates	Formaldehyde and its donor substances	Polybrominated diphenyl ethers
Amines	Fruits and vegetables, all types	Polychlorinated Biphenyls
Antioxidants	Fumaric acid and its esters	Polychlorinated Phenoxyphenols
Artificial sweeteners	Gelatin, hydrolyzed gelatin	Polysaccharides <sup>5</sup> other than composition <sup>6</sup>
Asbestos	Glycerin	Preservatives
Azo dyes	Glycols	Propolis
Azoles <sup>1</sup>	Heavy Metals	Purine alkaloids
Benzoic acid	Herbs, spices, all types	Pyrrrolizidine alkaloids
Benzoin	Iodine	Royal Jelly
Benzophenone	Lanolin	Salicylates
Bergamot oil	Latex, Natural Rubber	Silanes
Biogenic amines	Lectines	Silicones
Biocides	Melamine, Cyanuric acid	Sugar alcohols
Bisphenols and their derivates	Mica Ester	Sulfates
Boron or borates	Monosaccharides	Sulfonic acids
Cocamides	Natamycin	Sulfurous acid and its salts
Colophony	Nitrates	Sulfur
Colours	Nitrites	Talc
Coniferyl Alcohol	Oils and fats, vegetable and animal	Thiocyanates
Dehydroacetic acid	Oilseeds <sup>3</sup>	Thiuram disulfides
Diacetyl	Oligo- and polypeptides	Tributyltin
Dimethylfumarate	Organic poly- and their monomers <sup>4</sup>	Triglycerides
Dioxins	Parabenes	Volatile Organic Compounds
Disaccharides other than lactose	Peru balsam	Yeast
Ethanol	Phenols (Mono-, Di-, Tri- etc.)	
Fatty acids and their esters	Phenylalanin	
Flavourings, perfumes	Phthalates	
Flavouring substances <sup>2</sup>	Pollen	

### Remarks

<sup>1</sup> pyrrol, imidazole, pyrazole, triazoles, tetrazole, pentazole, oxazole, isoxazole, oxadiazoles, thiazole, isothiazole, thiadiazoles and the successively reduced analogues (azolines and azolidines)

<sup>2</sup> incl. substances mentioned in Regulation (EC) No 1334/2008, Annex I and Regulation (EC) No 1223/2009, Annex III Ref. numbers 67 – 92

<sup>3</sup> incl. poppy seed, sunflower seed, linseed

<sup>4</sup> incl. PE, PP, PVC, PS, PET and their monomers ethene, propene, vinyl chloride, styrene, terephthalic acid, ethylene glycol.

<sup>5</sup> incl. starch, cellulose, glycogen, chitin, dextran, chitosan, pectin, inulin, xanthan, arabinogalactan, galactomannan, alginate, carrageenan, guaran, carubin

<sup>6</sup> Co-processed excipients contain polysaccharides